

**INTERNATIONAL LAW ASSOCIATION**  
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**INTERNATIONAL LAW ON BIOTECHNOLOGY**

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**DRAFT REPORT\***

**INTRODUCTION AND BASIC TASKS**

Biotechnology, in particular genetic engineering, has been a fast growing technology mainly applied to medicines and foodstuffs. It creates a potential of enhanced welfare and growth in the field of life sciences and related economic activities, a potential to meet human needs in medicine, nutrition and fuels. At the same time, it poses considerable risks, for example to biodiversity, health and safety on which research is still scarce and not fully conclusive. This state of play poses considerable regulatory challenges in national, regional and international law. All novel technologies require the law to adjust and develop; yet, beyond the normal challenges, biotechnology also poses fundamental ethical problems which call for reflection as it touches upon the very foundations of life.

The ILA Committee on Biotechnology has been created with a view to addressing and analysing the regulatory needs resulting from biotechnology in international law. Much of the legal responses to biotechnology, so far, have been developed and can be found in national and regional law, in particular the law of the European Union. International law, as it exists, applies to the technology, but only a few special instruments have been developed which directly address the subject matter, the most prominent one being the Cartagena Protocol developed within, and under the auspices, of the Convention on Biological Diversity, and which implements the emerging precautionary principle.

The development of legal standards in the area of modern biotechnology is largely technology driven. Since its advent in the 1970s modern biotechnology leads to a large number of applications in different areas, in particular in medicine, agriculture and energy production. There are no uniform considerations that can be applied to these different fields. Rather each field of application presents its specific challenges to regulatory policies. This is particularly true when enquiring whether there is a need for rules on the level of international law, and for specific agreements, in particular.

Modern biotechnology has brought about a large number of practical applications. Humankind has made use of biotechnology for ages. Technological applications that use “biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use”<sup>1</sup> have been used to produce beer or yoghurt, conserve food, treat waste water and clean up toxic landscapes. However, only since the 1970s have “in vitro nucleic acid techniques” or “fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers”<sup>2</sup> – techniques referred to as “modern biotechnology” – become available. Since then a large number of applications in different fields have been developed. Best known are the

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\* The Committee extends its gratitude to Dr. Daniel Wüger for the extensive help with its activities and drafting this report. Dr. Wüger is a senior research fellow at the World Trade Institute in Berne and a lecturer at the University of Berne.

<sup>1</sup> Art. 2 Convention on Biological Diversity (CBD).

<sup>2</sup> Art. 3(i) Cartagena Protocol on Biosafety to CBD (Cartagena Protocol).

modification of seeds for agricultural production and the recombinant production of proteins for medical purposes, such as insulin, erythropoietin and therapeutic antibodies. The debate surrounding future medical treatments based on therapeutic cloning has drawn widespread attention. Yet, modern biotechnology applications are used or are being developed in a number of other areas such as industrial food production, production of pharmaceuticals with recombinant cell technology, breeding of farm animals, biofuel production, bio remediation and biometrics, basically in any area where organisms can be used for solving specific problems. The different applications require specific policy considerations adapted to their unique characteristics and stages of product development. The human health effects of the technologies vary according to the specific uses but also the hazards presented by the applications. A food product that is gested on a daily basis requires completely different policy considerations to a biofuel. Again a food-protein cannot be treated in the same way as a pharmaceutical. There is also a big difference between the regulation of biotechnology at the research stage as compared to its regulation when marketed. Similar considerations are valid for ethical or environmental implications relating to modern biotechnology. There are no unique characteristics that can be used as guidelines when regulating biotechnological applications. Rather, each field of application has to be looked at independently.

This is particularly true when asking the question whether modern biotechnology should be regulated in international law. This is most obvious when an application of modern biotechnology – for instance a field trial – is less likely to create transboundary effects. The need for international legal standards and their content requires careful examination. In some instances as e.g. market approvals for pharmaceuticals produced with modern biotechnology or local production facilities employing genetic engineering technologies, special international rules might not be feasible at all. Even where there is consensus that an international regulation might be feasible, other reasons might speak against an international agreement. Having different national solutions to the same regulatory problem might be preferable e.g. for ethical or religious reasons.

## **A MANDATE, WORK PLAN AND WORKING METHODS**

The Committee is mandated to examine the implications of international law as it exists, and to identify regulatory areas which would need to be addressed by future rules. A mandate is contained in the ILA newsletter No. 18, of 2003 (see also the Annex to this draft report). Based upon the large, but varying body of domestic law of different jurisdictions, it would seem important to address the proper role of international law and the question as to whether and how far it is necessary to improve rules on co-existence, on co-operation or to bring about harmonisation and integration of such rules and principles in order to meet the challenges and potential of the new technology on a global level and within the process of globalisation.

The Committee is not able to address all issues at the same time. There are limited resources, and ILA does not make available funding which would allow for the commissioning of research efforts on its behalf. The Committee has developed its priorities and, accordingly, a working plan to be pursued until 2010 when a final report of the Committee will be published. In cooperation with the World Trade Institute, Berne, the Committee has held a conference (World Trade Forum 2005) on biotechnology and international trade in September 2005. Several papers resulted from that conference which are currently being edited. The manuscript is scheduled to be finalized by end of May 2006.

This draft report has been based on these initial results. It identifies core working hypotheses and first results as well as work the Committee will pursue over the next two years. This report has been prepared by the Chairman of the Committee, Prof. Thomas Cottier. It was, subsequently, circulated to all Committee Members. The interim report was adopted by consensus on April 18, 2006.

## **B WORKING DEFINITIONS**

For the purpose of its tasks, the Committee has addressed and clarified the concept and notion of biotechnology and distinguished it from other, related technologies and methods in research and production. It distinguishes biotechnology as an overarching term including conventional technologies (such as breeding, traditional use of organisms in naturally occurring processes such as waste disposal) from genetic engineering and its applications in different scientific fields, often referred to as modern biotechnology.

The Committee has and might in the future consult scientists on the different forms and constellations of genetic engineering and the current state of research on risks and potentials they entail.

The Committee has adopted appropriate working definitions, based upon those already developed in international conventions and domestic jurisdictions. It will further clarify the bearing of the working definitions on the main areas of application of modern biotechnology, in particular agriculture and medicine and the differences between these different areas.

"Biotechnology":

“Biotechnological inventions are inventions which concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used.” (Rule 23 (b) § 2 to the EPC).

“‘Biotechnology’ means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.” (Article 2 of the Convention on Biodiversity).

“Modern Biotechnology”:

“Modern biotechnology means the application of: a. In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or b. Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection” (Article 3 (i) of the Cartagena Protocol on Biosafety to the Convention on Biodiversity, 5 June 1992, 39 International Legal Material 1027 (2000).

“Biological Material”:

“[A]ny material containing genetic information and capable of reproducing itself or being reproduced in a biological system.” (Rule 23 (b) (c) to the EPC and Article 2 (a) Directive 98/44/EC).

“Essentially Biological Process for the production of plants or animals”:

A process for the production of plants or animals will be essentially biological if: “it consists entirely of natural phenomena such as selective breeding” (Article 2 § 2 Directive 98/44/EC), or, more precise, “if it consists entirely of natural phenomena such as crossing or selection” (Rule 23 (b) (5) EPC).

“Living Organism”:

“Living organism” means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids; (Article 3 (h) of the Cartagena Protocol)

“Living Modified Organism”:

“Living modified organism” means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology (Article 3 (g) of the Cartagena Protocol)

“Genetic material”:

“‘Genetic Material’ means any material of plant, animal, microbial or other origin containing functional units of heredity.” (Art. 2 Convention on Biological Diversity).

“Genetic resources”:

“‘Genetic resources’ means genetic material of actual or potential value.” (Art. 2 Convention on Biological Diversity).

## **C HUMAN RIGHTS AND GOOD GOVERNANCE**

Human Rights in international law, but also in constitutional law, may provide the basis to assess ethical dimensions of biotechnology. It will be useful to identify not only pertinent guarantees, such as human dignity and personal liberty, but also the impact of social and economic rights. This will mainly be of importance to health, food and sustainable development, in particular in relationship to issues surrounding access to medicines and food security. Interfacing these different values with pertinent public interests and also the principles of permanent sovereignty over natural resources it may be possible to assist in narrowing down ethical differences and elaborate the basis for a common denominator which may inform more specific policies identified below. In this context, the Committee will also look into the implications of principles relating to procedural human rights, in particular due process, and principles of good governance, both for government and the private sector. Biotechnology raises many questions, which are of concern to civil society as the controversies surrounding agricultural biotechnology and human cloning illustrate. The Committee will examine whether there are any procedural imperatives in international law that are relevant for decision making on biotech issues and whether such rules should be developed in terms of international minimal standards which both provide a basis for, and monitoring and enforcing of, domestic standards. A specific issue is the question of how decisions are made, or priorities established, regarding research and product development vis-à-vis biotechnology. How should governments ensure that research is pursued in sectors of importance to society? Is active public sector research and development the right solution or should governments regulate private sector research activities, e.g. through the development of “ethical protocols” or the provision of specific incentives? Existing ethical protocols, such as the Right to Food Guidelines adopted by the FAO Intergovernmental Working Group in 2004,<sup>3</sup> work undertaken by the FAO Panel of Eminent Experts on Ethics in Food and Agriculture,<sup>4</sup> or the Global Compact for MNEs<sup>5</sup>

<sup>3</sup> Voluntary Guidelines to Support the Progressive Realisation of the Right to Adequate Food in the Context of National Food Security, adopted by the 127<sup>th</sup> Session of the FAO Council, November 2004, available at <http://www.fao.org/docrep/meeting/009/y9825e/y9825e00.htm> (last visited in April 2006).

<sup>4</sup> Report of the Panel of Eminent Experts on Ethics in Food and Agriculture, Second session, 18-20 March 2002, available at [http://www.fao.org/documents/advanced\\_s\\_result.asp](http://www.fao.org/documents/advanced_s_result.asp) (last visited in April 2006).

might also yield insights for the field of genetic engineering. The core question to be addressed is whether and what role international law should play in these processes and policy choices primarily made at national and regional levels.

The Committee has adopted the following working hypotheses on which it will endeavour to provide specific recommendations within the next two years:

- A number of human rights standards are relevant to modern biotechnology and its applications. The rights include foremost the right to life, individual freedom, freedom of religion and beliefs, right to privacy, prohibition of discrimination, right to information as well as scientific freedom.
  - o A limited number of *ius cogens* aspects can be identified that are of relevance to activities involving applications of modern biotechnology.

Within the next two years, the Committee will undertake to further explore *ius cogens* aspects of modern biotechnology. It will also examine the relevance of the concept of “non-derogatory rights” (see e.g. Art. 15.2 European Convention on Human Rights) and its implications for the international law on modern biotechnology, i.e. rights which, at no circumstance, may be restricted.

- Modern biotechnology raises important questions of human rights policy that inform legislation and policy formulation on a national and international level. Only limited attention has been given to the question whether such aspects need to be examined or whether there might be a need for special international legal rules. Questions with relevance to human rights policy that will be examined further by the Committee in the next two years could include:
  - o Genetic information and discrimination: Information on the genetic make-up and predisposition of humans for certain conditions bears a potential for discrimination which needs to obtain more attention from international policy makers. Such discrimination might be undesirable for the international community. Some evidence can be found in the Universal Declaration on the Human Genome and Human rights<sup>6</sup> and Universal Declaration on Bioethics and Human Rights.<sup>7</sup> Examples could include
    - the availability of medical services based on genetic pre-disposition for certain diseases;
    - the availability and conditioning of private and social insurance based on certain genetic pre-dispositions;
    - the conditions under which research on human DNA can be conducted, information collected and in what ways it can be used (see also below on liability) taking note of the International Declaration on Human Genetic Data;<sup>8</sup>
    - the relationship of biotechnology and the law of warfare, in particular the Geneva Conventions.
  - o Is there a need for the negotiation of basic international procedural standards that could help to avoid discrimination based on genetic information?
  - o What is the potential contribution of the principle of subsidiarity or the principle of proportionality to the question of what aspects of modern biotechnology should be regulated at the international level?
- Modern biotechnology raises a number of important ethical questions, foremost relating to human dignity. The Committee will, in the next two years, undertake further work on the question of whether there is a need for international legal rules fostering the mainstreaming of ethical considerations into the international and national debate on modern biotechnology (see also next point relating to good governance). In

<sup>5</sup> The UN Global Compact and the OECD Guidelines for Multinational Enterprises: Complementarities and Distinctive Contributions, 26 April 2005, available at <http://www.oecd.org/dataoecd/23/2/34873731.pdf> (last visited in April 2006).

<sup>6</sup> The text of this Declaration, adopted by the UNESCO General Conference at its 29th session in 1997 (Resolution 29 C/16), is available at [http://www.unesco.org/legal\\_instruments](http://www.unesco.org/legal_instruments) (last visited in October 2005).

<sup>7</sup> The text of this Declaration, adopted on 19<sup>th</sup> October 2005 by the 33<sup>rd</sup> session of the General Conference of UNESCO, available at [http://portal.unesco.org/shs/en/file\\_download.php/46133e1f4691e4c6e57566763d474a4dBioethicsDeclaration\\_EN.pdf](http://portal.unesco.org/shs/en/file_download.php/46133e1f4691e4c6e57566763d474a4dBioethicsDeclaration_EN.pdf) (last visited in April 2006).

<sup>8</sup> The text of this Declaration, adopted at the 32nd Session of the General Conference in 2003 (Resolution 32 C/22) is available at [http://www.unesco.org/legal\\_instruments](http://www.unesco.org/legal_instruments) (last visited in October 2005).

particular, it will examine the normative impact of human dignity, given the fact that the same technology may be used in support of, and to the detriment, of human dignity.

- There are important aspects of good governance that have to be examined bearing in mind the specificities of the various applications of modern human biotechnology. The Committee, taking note of the principles of the Aarhus Convention,<sup>9</sup> will undertake to further identify such issues, including but not limited to the following:
  - o Is there a need for international procedural measures safeguarding the input of ethical aspects relating to medical applications of modern biotechnology? In how far should there be international legal rules on national ethics committees? What is the appropriate role for ethics committees in modern biotechnology policy making?
  - o What procedural rights should individuals have relating to the various uses of their genetic information?

## **D PROPRIETARY RIGHTS AND PUBLIC DOMAIN: PUBLIC GOODS**

An important regulatory area relates to proprietary rights on biotechnological innovations. There is a debate on whether patenting is the appropriate instrument protecting commercial rights in biotechnological innovations. In particular, where living organisms are part of such innovations, it has been questioned whether the granting of exclusivity rights is appropriate. The Committee is assessing the current state of play in main jurisdictions of developed and developing economies and assesses the implication of patenting on investment (variously within the public and private sectors), market power, competition, distribution of benefits derived through the use of biological resources and impacts on biodiversity.

The Committee acknowledges that extensive work has been done in this field. Binding legal rules exist, in particular, in the TRIPs Agreement of the WTO, the Convention on Biological Diversity (CBD) and regional instruments, such as the EC biotech patent directive<sup>10</sup> and the European Patent Convention (EPC).<sup>11</sup> It is examining, whether these legal rules as well as other work undertaken in various international *fora* is coherent and, if need be, what action is needed to bring about more coherence. The Committee is also assessing research undertaken in this field.

The main working hypothesis of the Committee is, that public goods must be promoted by using a proper mix of proprietary rights and public policies. Thus, the Committee is evaluating whether the existing legal rules governing the acquisition of proprietary rights in the field of biotechnology, including rights in intellectual property, negatively impact on public goods, and, if so, where such deficiencies can be remedied with the help of internationally applicable legal instruments. Other working hypotheses on which the Committee will examine whether specific ILA recommendations can contribute to an informed debate include:

- The Committee acknowledges that the patent system is one of the suitable alternatives for granting proprietary rights on biogenetic inventions. Among others, it is working on the following topics:
  - o the limits of patentability, such as for example the basic distinction of discovery and invention, the limits of the rights conferred to the patent holder, the ethical dimension in the field and the impact of patenting life forms in different walks of life. Furthermore, it is looking at the effect of proprietary rights on the use of trade secrets and the protection of undisclosed information.
  - o the ethical implications of patents on biogenetic inventions, including ethical limitations to patenting. It is also looking at the connection to human rights and proprietary rights of DNA and human tissue donors.
  - o the scope of patent rights as applied to genetic engineering, in particular as to whether special rules are required in terms of specific rights, fair use exemptions and exhaustion of rights.
- The Committee is looking into the terms of access and benefit sharing under the assumption that an adequate balance has to be struck between countries that have an interest in promoting their biogenetic

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<sup>9</sup> Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters, done at Aarhus, Denmark, on 25 June 1998, available at <http://www.unece.org/env/pp/documents/cep43e.pdf> (last visited in April 2006).

<sup>10</sup> Directive 98/44/EC of the European Parliament and of the Council of 6<sup>th</sup> July 1998 on the Legal Protection of Biotechnological Inventions, available at [http://europa.eu.int/eur-lex/pri/en/oj/dat/1998/l\\_213/l\\_21319980730en00130021.pdf](http://europa.eu.int/eur-lex/pri/en/oj/dat/1998/l_213/l_21319980730en00130021.pdf) (last visited in April 2006).

<sup>11</sup> Convention on the Grant of European Patents (European Patent Convention) of 5 October 1973, available at <http://www.european-patent-office.org/legal/epc/e/ma1.html#CVN> (last visited in April 2006).

industry and countries that are the main trustees of large biogenetic resources. Among others, it is taking into account the following factors:

- that poverty can be a factor detrimental to biodiversity and that appropriate terms of access and benefit sharing may be a means to counteract this factor. In this context, it will examine potential obligations, currently proposed, to disclose the geographical source of materials supporting the invention and the concept of prior informed consent;
  - the implications of traditional knowledge and how it can best be protected with a view to alleviate poverty and to make a contribution in preserving biodiversity, mainly in developing countries where 95 % of all biologically rich areas are located;
  - the economic benefits that countries of large biogenetic resources may obtain through better use of their property rights to genetic resources and traditional knowledge;
  - the Committee is interested in the legal vehicles available for benefit sharing (voluntary licensing, compulsory licensing, patent pooling, joint ownership of rights / joint ventures etc.); and
  - the Committee is interested in the role international organizations may have in monitoring and promoting the fairness of the respective shares in the benefits derived from biotechnological progress.
- The Committee is stressing, that so far too little attention has been given to animal genetic resources and plant genetic resources beyond agricultural crops so far. The international Community needs to think more about other applications of modern biotechnology including applications in the fields of pharmaceuticals, bio-based energy, bio-remediation and other industrial applications. More research has to be done that can help to establish the needs for international rules in this area.
- The Committee also considers whether a *sui generis* intellectual property system could provide adequate protection for biogenetic inventions. It will need to examine the relationship of patent protection and plant variety protection, in particular by the UPOV Convention, and other *sui generis* systems developed under Article 27(3)(b) of the TRIPs Agreement. The Committee is interested in the efficiency of technology-specific intellectual property systems (such as the UPOV *sui generis* system), as well as proposals that have been made to adapt existing non-technology specific systems to the needs of biotechnology. Reference is made to the legislative trend (e.g. in Germany and France) to establish purpose-limited protection in the field of biotechnology, as distinguished from absolute protection granted for all other types of product inventions.<sup>12</sup>
- The Committee considers the call for interfacing the patent system and the protection of traditional knowledge. For that purpose, it is studying the implications of granting proprietary rights on genetic resources connected with traditional knowledge, traditional medicine and biodiversity. It will examine proposals made to create so-called Traditional Intellectual Property Rights (TIP rights), emanating from, and based upon, the concept of unfair competition. It is taking into account the work undertaken under the CBD and the current negotiations being pursued to develop a binding protocol on access and benefit sharing. Similarly, it is studying the implications for plant breeding and related instruments, such as the UPOV Convention and alternatives, and the FAO International Treaty on Plant Genetic Resources for Food and Agriculture. The specific questions it is looking at include:
- What specific instruments in the field of patents can help facilitate an appropriate interface between proprietary rights and traditional knowledge: prior informed consent, enhanced registration of prior art? Would a *sui generis* system provide for an appropriate balance?
  - What proprietary rights' needs does a research-based economy have? Are there distinct needs with regard to proprietary rights of countries in course of development? Can the existing legal framework for IPRs accommodate any divergent needs?
  - What are the appropriate objectives of protecting traditional knowledge (safeguarding traditional cultures; securing the livelihoods of rural peoples; protection of biodiversity?) and what are the most suitable instruments (*sui generis* system *versus* patent system; international *versus* national protection) of protection?

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<sup>12</sup> see e.g. §1(a) of the German Patent Act (GPA) implementing EU Directive 98/44/EC, available at <http://www.bgbportal.de/BGBL/bgb1f/bgb1105s0146.pdf> (last visited in April 2006).

## E MARKET ACCESS

Biotechnology poses a number of difficult problems in the field of market access and thus international trade regulation. Concerns over the safety of modern biotechnology's applications, especially in the field of agriculture, have led to a number of diverging national approaches concerning the costs and benefits of the new technological applications. These approaches are translated into market access issues by means of approval procedures, consumer information policies, traceability requirements, special liability rules (see next chapter), etc. The different legal regimes again vary from one field of application to another.

Much work on the application of current trade rules of the WTO and regional and bilateral agreements to the technology has been done. Nevertheless, the Committee considers that there is still need for further assessment, especially on the implications of the general rules of the GATT 1994 and other WTO Agreements, in particular the SPS Agreement, the TBT Agreement and the TRIPs Agreement and how they can be interfaced with the Cartagena Protocol and the Convention on Biodiversity. Besides existing research, the Committee is following the *EC – Biotech* dispute between the EC and Argentina, Canada the U.S. with heightened attention. The Committee's work partly draws on research undertaken on the complex linkages of trade rules and multilateral environmental agreements (MEAs).

- The Committee is looking at existing GATT principles and rules and other WTO agreements and their bearing on the many applications of modern biotechnology. There are a number of specific questions that the Committee is pursuing:
  - Which rules apply to the different forms of biotechnology? Does the TBT Agreement, the SPS Agreement and/or the GATT 1994 apply? And what are the implications of these Agreements?
  - What is the role of the concept of like products in the field of biotechnology? How should rules on process and production standards (PPMs) be assessed in this field?
  - What is an appropriate standard of deference to national policies in the field of biotechnology? Should they be different depending on the field of application?
  - Is there a need for a Special Agreement on Biotechnology within the WTO and, if so, what should it regulate?
  - What should be the appropriate role for international standard setting bodies in this field? Should it be restricted to providing procedural guidelines such as norms on risk assessment and risk management techniques? Should they provide standards on specific GMOs and products produced from GMOs? Should they provide general GMO health and safety standards?
  
- The interface between MEAs and international trade rules has made progress in WTO dispute settlement, but overall become more controversial since the end of the Uruguay Round. There are, currently, negotiations in the Doha Development Agenda (DDA) on the subject. In the field of modern biotechnology, discussions have centred mainly on the relation of the Cartagena Protocol, WTO rules and the application of the precautionary principle. Further work is necessary though. There are a number of issues the Committee is pursuing:
  - Whether the international trading system can learn from how a similar conflict was dealt with at the regional (and bilateral) level. Many regional trade agreements have dealt with the issue on a general as well as on a specific level. Indeed, WTO practice has shown some development in that area and regional/domestic courts have tried to synchronize regional rules with world trade rules. Important contributions for the MEA debate could result from comparative work, which takes such practice into account.
  - And related to that are more general methodological questions. How can the general international law rules on interpretation (including those contained in the Vienna Convention on the Law of Treaties) be used to create a workable interface between environmental and trade rules? To what extent can international environmental rules, including the Cartagena Protocol, be used as an aid to interpretation of trade rules? In how far can emerging principles, such as the principle of mutual supportiveness, contribute to that interface?
  - What lessons can be drawn from leading cases adjudicated by WTO panels and the Appellate Body?
  
- The connection between consumer protection policies and market access is not a new one. However, a new angle has been developed by some States using so-called “consumer information” measures as tools to correct market imbalances. Often, States use labelling systems for such purposes. The Committee considers that the number of disputes in this area will increase in the future and that there is a need for research on whether traditional rules on market access are suitable for this new type of consumer information policies.

- An important issue, which has not received enough attention so far, is the application of special and differential treatment to developing countries in the SPS/TBT area. There are two basic positions; one stressing that developed countries cannot be forced to relax their safety standards because of S&D considerations and that there should not be a trade off between safety and development. The other position stresses that developing countries' participation in international standard setting institutions should be enhanced. In the Committee's view, both points are well taken. Nevertheless, it considers that there is need for a better understanding of developing countries' needs and for further creative thinking on how they can be taken into account under the existing rules. The Committee considers that, at this point, not enough is known to be in a position to decide whether there is a need for new or different legal rules. During the next two years, it will engage in following the debate with the intention of putting forward some of its own recommendations. In this context, it will take into account ongoing work on graduation and ideas of progressive regulation set forth.

## **F LIABILITY AND STATE RESPONSIBILITY**

While the areas of proprietary rights and trade have been addressed and established in international law, it seems that this has not been the case beyond discussions held within the Convention on Biological Diversity for questions relating to compensation for adverse effects of biotechnology. The Committee is examining angles of state responsibility and liability. While each of these latter issues merits separate treatment, there are connected questions pertaining to both, for example the classification of the effects of GMOs as causation, damage, the issue of unlawfulness, and fault. Also, in both areas, general rules exist. Yet, there is disagreement as to how far the general rules can account for all forms of undesired effects that can result from applications of modern biotechnology and whether liability and state responsibility are the appropriate tools for counteracting such effects. Within the next two years, the Committee will endeavour to come up with its own recommendations. Specifically, it is looking at the following issues:

- In the area of liability, defining costs of research, production and competition, and potential damages, and thus of insurance and financial security, has been largely left to principles of tort law in a national or perhaps regional context. There are only few national legislations that have started to enact special liability regimes for modern biotechnological applications.
  - Is there a need for harmonisation of liability rules in the field of biotechnology? What would be an appropriate standard in international law for product liability? Under what circumstances is it justified to speak of injury and who is the injured party?
  - Who should be liable for the different uses that biotechnological applications entail? What are the implications of 'strict' liability and 'fault-based' liability on technological progress, competition or the preponderance of injurious acts?
  - Should the prevention of damage to biodiversity be supported by criminal sanctions?
- A special angle to the problem results from modern human biotechnology (see above under human rights policies). The Committee will undertake further work on the appropriate consequences that should result from the use of information on the genetic makeup of an individual without his or her consent.
- In the area of state responsibility, the committee is looking into special problems that might arise from the use of modern biotechnology. Its work is based on the Draft Articles on State Responsibility<sup>13</sup> of the International Law Commission and includes the following issues:
  - Biotechnology raises important questions with regard to state attribution. While injurious acts will regularly be committed by private individuals, GMOs have to undergo rigorous testing and approval procedures before being released into the environment. The Committee considers that there is a need for further thinking on whether such acts can and should be attributed to States.
  - How can damages to biological diversity be assessed and quantified? In many cases, there might not be an easily quantifiable remedy once damage is caused, for example where *restitutio in integrum* is sought. Where the cost of a remedy cannot be used to calculate injury are there alternative concepts that can be used to arrive at such a calculation? Should special rules on injury be negotiated in the framework of the CBD or in another international instrument?
  - The Committee also considers that specific attention should be given as to the use of eventual damages to be paid. Despite biological resources being attributed to individual States, there is a

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<sup>13</sup> Draft articles on Responsibility of States for internationally wrongful acts, adopted by the International Law Commission at its 53<sup>rd</sup> session (2001), available at <http://www.ilsa.org/jessup/jessup06/basicmats2/DASR.pdf> (last visited in April 2006).

considerable common interest in biodiversity. The Committee is examining, whether eventual damages from State responsibility should be tied to certain uses to the benefit of biodiversity. The Committee is also considering, whether state responsibility in the field of modern biotechnology requires special compliance mechanisms.

- Related to the last point, the Committee is looking into the question to whom responsibility is owed, including the application of Arts. 46-48 of the Draft Articles on State Responsibility.
  - The Committee also examines the impact of diverging liability regimes on costs and market access. It will examine implications of WTO law, in particular the concept of non-violation nullification and impairments of benefits.
- There are a number of common questions the Committee is looking at under its work program. These questions include the following:
- Does out-crossing of GM crops into conventional crops (wild species, ex situ collections, national seed supply systems) create injury?
  - The Committee considers that the issue of the influence of natural forces on the transfer of DNA needs special attention with regard to the concept of “unlawfulness”. The question arises both in the context of liability and state responsibility.
  - From an economic point of view, diverging standards of liability amount to considerable distortions of market access (see above). At the same time, they form an important element, together with the admission of research and marketing approval, of competitive advantages and disadvantages, which can be gained from different regulatory approaches in different jurisdictions. Additionally, in certain areas of modern biotechnology, there might also be a danger of a “race to the bottom” to attract investment.

### **Mandate of the ILA Committee on International Law and Biotechnology**

Biotechnology regulation cuts across many areas of law, public, private, national, regional and international. The Committee would seek to focus on aspects of international law of biotechnology regulation, and take national regulations into account to the extent required to understand and further develop international law rules.

1. Consideration would need to be given to the regulation of biotechnology per se in relation to intellectual property (TRIPs, patent harmonization, EPO et al), to environmentally motivated regulations (Cartagena Protocol), to Food standards and TBT (SPS Agreement and TBT Agreement) and possible future instruments to be developed, for example in relation to market approval rules, labelling rules and production and process methods. We also will need to address liability rules which, as it seems, are currently far from harmonized and create uneven playing level fields for the industry, ranging from product liability to strict liability rules in some countries.

2. Consideration will also need to be given to side effects of biotechnology, in particular in agricultural policies. We would need to look into the potential of enhancing the protection of traditional knowledge in order to counterbalance the potential of patenting of biotechnology. This is an area of law in development (both in WIPO and WTO). Main areas will need to focus on the law of plant genetic resources for agriculture and the relationship with the International Treaty on Plant Genetic Resources for Food and Agriculture of FAO.

3. Work would need to be coordinated with other Committees, in particular the International Trade Law Committee which may deal with specific related aspects.